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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/344,382	06/25/1999	SHUNICHI SOMA	050499/0101	9000

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EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 04/08/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/344,382

Applicant(s)

SOMA ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-50 is/are pending in the application.
- 4a) Of the above claim(s) 29-42, 44 and 46-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-28, 43, 45, 49 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 22-50 are pending. Claims 29-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 4.

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Applicant's election of group I and the species that encompass continuous, systemic administration of PTH(1-34) in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

10

Claims 22-28, 43-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to, or to the extent that they are drawn to, a nonelected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

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Claims 22-28, 43, 45, 49, 50 are being examined to the extent that they read upon the elected invention and/or species. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

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Maintained Formal Matters, Objections, and/or Rejections:

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

- 5 An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). 37 CFR § 1.78 (a)(2) provides that except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior filed copending
- 10 nonprovisional applications or international applications designating the United States of America must contain a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. The amendment in the specification, on page 1 after the Title, filed
- 15 September 4, 2001 (Paper No. 10) does not indicate the relationship of the applications.

Claim Rejections - 35 USC § 112

- Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for parathyroid hormone, does not reasonably provide enablement for a
- 20 derivative thereof.

The rejection of record is applied to claims 43, 49, 50.

Applicants argue that PTH derivatives are well known in the art (referring to Potts), that the minimal amino acid sequence required for activity has been defined, that the evolutionarily conserved residues have been shown, that one skilled in the art could easily produce a PTH derivative. Applicants arguments have been fully considered but they are not persuasive. In contrast to a derivative comprising a minimal amino acid sequence required for activity or a derivative comprising evolutionarily conserved residues, there are no structural limitations to the "derivative" as claimed. The claims encompass not only a derivative comprising a minimal amino acid sequence required for activity or a derivative comprising evolutionarily conserved residues, but also encompass the use of any and all conceivable compounds, including those that are structurally unrelated to PTH, because there are no structural limitations to the "derivative" as claimed. It is this additional characterization of either PTH, a minimal fragment thereof, or a PTH derivative comprising evolutionarily conserved residues of PTH, that is required for the skilled artisan to make other compounds structurally unrelated to PTH in order to practice the scope of Applicants' claimed invention in view of the lack of guidance for making, and working examples of, compounds structurally unrelated to PTH that constitutes undue experimentation.

Claim Rejections - 35 USC § 102

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Kamata (A6, cited by Applicants).

Applicants argue that Kamata does not teach the administration of PTH, that there is no indication that the rats were in need of tooth movement, that Kamata does not provide any evidence of tooth movement as a result of PTH administration. Applicants arguments have been

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fully considered but they are not persuasive. There is no evidence of record that Kamata's parathyroid gland extract did not contain PTH, and the present application's specification, at page 3, full paragraph 1, appears to acknowledge the presence of PTH and the role that PTH plays in tooth movement in Kamata's parathyroid gland extract. There is no evidence of record that an impurity in Kamata's parathyroid gland extract is responsible for the results. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., purity of the extract) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. There are no structural limitations to the "derivative" as claimed, and Kamata's parathyroid gland extract contains PTH and/or a PTH derivative. That the rats were subjects in need of tooth movement is apparent by the tooth movement seen therein. See Kamata at page 415, full paragraph 1. The present application at page 16 and figures 2 and 3 note tooth movement at 48 hours, which is the length of time used by Kamata, and the histological changes seen by Kamata are consistent with the changes seen by Applicants in the present application at paragraph bridging pages 16-17 and Figure 4. The results in Kamata are consistent with an increase in tooth movement, in the absence of evidence to the contrary. It is further noted that Kamata treated the rats daily with a subcutaneous injection of parathyroid extract (page 413, full paragraph 1). Daily treatment with parathyroid extract is administering multiple times. The administration was continuous over the period of injection.

Claim Rejections - 35 USC § 103

Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianelly (w6) in view of Kronenberg (A1, cited by Applicants), Gardella (A7, cited by Applicants), and Sindrey (A2, cited by Applicants).

5 The rejection of record is applied to claim 43 because PTH(1-34), as taught by Kronenberg or Gardella is a peptide fragment of PTH, a peptide constructed by partly deleting one or more amino acids of PTH or a peptide fragment thereof, a peptide fragment of a peptide constructed by adding one or more amino acids to PTH per se.

 The rejection of record is applied to claim 45.

10 Applicants argue that Gianelly provides no evidence to suggest that a single injection of PTH is sufficient for an orthodontic remedy, that the combination of references fails to suggest the benefit of multiple or continuous administration of PTH or a PTH derivative as an orthodontic remedy. Applicants arguments have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features
15 of applicant's invention, it is noted that the features upon which applicant relies (i.e., a single injection) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer the PTH multiple times or continuously, with a reasonable expectation of success.
20 The administration of the PTH is continuous over the duration of the administration. One of ordinary skill in the art would be motivated to administer the PTH multiple times or continuously

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in order to achieve the requisite amount of orthodontic tooth movement. The invention is prima facie obvious over the prior art.

New formal matters, objections, and/or rejections:

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Claim Rejections - 35 USC § 102

Claims 22, 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Davidovitch (u13). This rejection is being made in part in the event that the rejection of claim 22 under 35 U.S.C. 102(b) as being anticipated by Kamata (A6, cited by Applicants) is overcome by a showing of evidence that Kamata's method did not result in an increase in tooth movement, said increase in tooth movement a new limitation introduced by Applicant's amendment and necessitating further consideration and the new ground(s) of rejection. Davidovitch teaches administering an amount of PTH or a PTH derivative, that results in an increase in tooth movement (page 96, full paragraph 2). That the cats were subjects in need of tooth movement is apparent by the tooth movement seen therein. The PTH is administered systemically (page 95, full paragraph 1) by intramuscular injections (page 95, full paragraph 3). Daily injection is administering multiple times. An injection is continuous over the time of the injection.

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Claim Rejections - 35 USC § 103

Claims 22, 49, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidovitch (u13) and Schluter (a13). This rejection is being made in part in the event that the rejection of claim 22 under 35 U.S.C. 102(b) as being anticipated by Kamata (A6, cited by Applicants) is overcome by a showing of evidence that Kamata's method did not result in an

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increase in tooth movement, said increase in tooth movement a new limitation introduced by Applicant's amendment and necessitating further consideration and the new ground(s) of rejection. Davidovitch teaches administering an amount of PTH or a PTH derivative, that results in an increase in tooth movement (page 96, full paragraph 2). That the cats were subjects in need of tooth movement is apparent by the tooth movement seen therein. The PTH is administered systemically (page 95, full paragraph 1) by intramuscular injections (page 95, full paragraph 3). Daily injection is administering multiple times. An injection is continuous over the time of the injection. Davidovitch does not teach administration of PTH in a composition comprising PEG. Schluter teaches pharmaceutical dosage unit forms for systemic (parenteral) administration of PTH, which are useful for the mitogenic and bone growth effect in mammals. The term "dosage unit form" as used in this specification and in the claims refers to physically discrete units suitable as unitary dosages for mammalian subjects, each unit containing a predetermined quantity of the essential active ingredient, i.e., a modified PTH, calculated to produce the desired effect in combination with the required pharmaceutical means which adapt said ingredient for systemic administration. Examples of dosage unit forms in accordance with this invention are sterile preparations in liquid vehicles for parenteral administration and sterile dry preparations for the extemporaneous preparation of sterile injectable preparations in a liquid vehicle. Carriers or vehicles include liquid polyethylene glycol. See paragraph bridging columns 11-12. Schluter does not teach systemic (parenteral) administration of PTH in a preparation comprising PEG that results in tooth movement in a subject in need thereof. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer an amount of PTH or a PTH derivative, that results in an increase in tooth movement, as taught by

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Davidovitch, and to modify that teaching by systemic (parenteral) administration of PTH in a preparation comprising PEG, as taught by Schluter, with a reasonable expectation of success.

One of ordinary skill in the art would be motivated to combine these teachings in order to produce the desired effect (assist orthodontic tooth movement) in combination with the required

5 pharmaceutical means (PEG) which adapt PTH for systemic administration. The invention is prima facie obvious over the prior art.

Claim Rejections - 35 USC § 112

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being
10 indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 appears to have a misplaced colon (“:”) in line 2 which renders interpretation of the claim ambiguous. The metes and bounds are not clearly set forth.

Claim 43 recites the limitation “each having the same biological effect”. The antecedent
15 basis for this limitation is unclear. The metes and bounds are not clearly set forth.

Claim 43 recites the limitation “a peptide fragment thereof” at several instances. At each of such instances the antecedent basis for this limitation is unclear.

Conclusion

20 The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Takano-Yamamoto (A18, cited by Applicants) teaches that simultaneous application of mechanical and chemical or electrical stimuli acting in combination, might lead to more rapid

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bone turnover and, hence, faster orthodontic tooth movement that with mechanical orthodontic force alone (page 53, right column, full paragraph 1); the direct biological removal of alveolar bone by means of bone resorptive agents prior to orthodontic force application may decrease the resistance to tooth movement, thereby permitting selective tooth movement (page 58, left column, last paragraph).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

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DSR
APRIL 7, 2002